510(k) Summary

General Provisions	Correspondent Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 65 Great Valley Parkway Malvern, PA 19355 (610) 651-5046 (801) 545-4285 Alina Stubbs August 23, 2013 2529252
Subject Device	Trade Name: Common/Usual Name: Classification Name:	HeartSpan™ Fixed Curve Braided Transseptal Sheath Transseptal Introducer Kit Catheter Introducer (21 CFR §870.1340)
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	HeartSpan™ Fixed Curve Braided Transseptal Sheath Catheter Introducer (21 CFR §870.1340) K004026 – Braided Guiding Introducer Merit Medical Systems, Inc. 65 Great Valley Parkway Malvern, PA 19355 (formerly operating as Thomas Medical Products, Inc.)
Classification	Class II 21 CFR §870.1340 FDA Product Code: DYB Review Panel: Cardiovascular	
Intended Use	The HeartSpan™ Fixed Curve Braided Transseptal Sheath is indicated "For the percutaneous introduction of various types of cardiovascular catheters to all heart chambers, including the left atrium via transseptal puncture."	

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Device Description

The modified HeartSpan™ Fixed Curve Braided Transseptal Sheath consists of a dilator, guidewire, and fixed curve sheath, which are designed for catheter introduction into the cardiac anatomy. The device is provided sterile (ethylene oxide) and intended for single use only. It is for use in hospitals or healthcare facilities.

The fixed curve introducer contains a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A side-port with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring. The introducer is available in lengths ranging from 60 to 101.5 cm and curve configurations from 15° to 150° to address various anatomical features. The fixed curve introducer also includes distal perfusion holes to facilitate aspiration and minimize cavitation, a radiopaque tip marker to improve fluoroscopic visualization, an atraumatic soft tip, and a lubricious coating on the inner and outer surfaces. The dilator is designed to conform to the inner diameter of the sheath, and has a tapered tip.

The materials of construction are primarily polymers with the exception of stainless steel braid reinforcement wires in the introducer shaft that are completely encapsulated in the sheath wall and do not contact the patient or bodily fluids.

Comparison to Predicate

Summary of the technological characteristics of the modified device compared to the predicate devices:

Technical Characteristics	Predicate Device (K004026)	Modified Device (K132720)
Hemostasis valve provided	Yes	Yes
Dilator to Guide wire Compatibility	up to 0.038"	up to 0.038"
Compatibility with Standard Transseptal Needle	Yes	Yes
Length	30 cm min.	60 – 101.5 cm
French size	8.5F & 9.5F	8.5F
Curve	0° - 180°	15° - 150°
Wire braid reinforcement completely encapsulated	Yes	Yes
Radiopaque tip or marker	Yes	Yes
Soft Atraumatic Tip	Yes	Yes
Side port for infusion and contrast injection	Yes	Yes
UV and Thermal Stabilization in Sheath Tube and Tip	No	Yes
Distal perfusion holes	No	Yes

International Standards	No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for this device. Performance testing of the modified HeartSpan™ Fixed Curve Braided Transseptal Sheath was conducted based on the risk analysis and based on the requirements of the following international standards: • ISO 10993-1:2009 Evaluation of Medical Devices – Part 1: Evaluation and testing within a Risk Management Process • ISO 10993-4:2002/Amendment I 2002, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood • ISO 10993-5:2009, Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity • ISO 10993-7: 2008, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals • ISO 10993-10:2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization • ISO 10993-11:2006, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity • ISO 11070:1998, Sterile Single-Use Intravascular Catheter Introducers – Annex C • ANSI/AAMI/ISO 11135-1:2007, Sterilization of Health Care Products – Ethylene oxide – Part 1: Requirements for Development, Validation and Routine Control of Sterilization Process for Medical Devices

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Safety & Performance Tests

The modified HeartSpan™ Fixed Curve Braided Transseptal Sheath has been thoroughly tested through verification of product specifications and user requirements. The following quality assurance measures were applied during the development of the modified HeartSpan™ Fixed Curve Braided Transseptal Sheath:

- Risk Analysis
- Requirements/Specification Reviews
- Design Reviews
- Sterilization validation (ethylene oxide)
- Biocompatibility Testing (Verification)
- Performance Testing (Verification) listed below:
  - Sheath Tube Inner Diameter
  - Sheath Tube Outer Diameter
  - Sheath Free Length
  - Sheath Tip Inner Diameter
  - Sheath Visual Inspection
    - Curve Orientation
    - Sheath Curve Form
    - Breakaway Flash
    - Protruding wires or marker band
    - Tip Defects
    - Bumps or protrusion on tube
  - Sheath tip transition to dilator
  - Visual inspection of sheath inner surface
  - Simulated Use Test
  - Valve housing to tube joint integrity
  - Sheath Tube Delamination
  - Sheath Tip Integrity
  - Sheath Tip to Tube Joint Integrity
  - Sheath Tip Bend Back

The results of the testing demonstrated that the modified HeartSpan™ Fixed Curve Braided Transseptal Sheath meets the predetermined acceptance criteria applicable to safety and efficacy of the device.

Summary of Substantial Equivalence

Merit Medical Systems, Inc. considers the modified HeartSpan™ Fixed Curve Braided Transseptal Sheath substantially equivalent to the currently marketed predicate device (Braided Guiding Introducer - K004026). This assessment is based upon analysis of similar technological characteristics, bench testing, and indications for use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 12, 2014

Merit Medical Systems, Inc.
Ms. Alina Stubbs
Regulatory Affairs Specialist II
65 Great Valley Parkway
Malvern, PA 19355

Re: K132720
Trade Name: HeartSpan™ Fixed Curve Braided Transseptal Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: January 10, 2014
Received: January 13, 2014

Dear Ms. Stubbs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): K132720

Device Name: HeartSpan™ Fixed Curve Braided Transseptal Sheath

Indications for Use:

For the percutaneous introduction of various types of cardiovascular catheters to all heart chambers, including the left atrium via transseptal puncture.

Prescription Use __X___ AND/OR Over-The-Counter-Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)